



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 411

[CMS-6047-ANPRM]

RIN 0938-AR43

Medicare Program; Medicare Secondary Payer and "Future Medicals"

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This advance notice of proposed rulemaking solicits comment on standardized options that we are considering making available to beneficiaries and their representatives to clarify how they can meet their obligations to protect Medicare's interest with respect to Medicare Secondary Payer (MSP) claims involving automobile and liability insurance (including self-insurance), no-fault insurance, and workers' compensation when future medical care is claimed or the settlement, judgment, award, or other payment releases (or has the effect of releasing) claims for future medical care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-6047-ANPRM. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed).

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the instructions under the "More Search Options" tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-6047-ANPRM

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-6047-ANPRM,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, D.C.--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW,
Washington, D.C. 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Suzanne Kalwa, (410) 786-2536.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please phone 1-800-743-3951.

I. Overview and Background

We are issuing this advance notice of proposed rulemaking (ANPRM) to solicit public comments on standardized options that beneficiaries and their attorneys or other representatives will be able to use to resolve MSP obligations related to settlements, judgments, awards, or other payments (hereinafter, for ease of reference in this document and unless otherwise indicated, "settlement(s)") involving future medical care while protecting Medicare's interest.

When the Medicare program was enacted in 1965, Medicare was the primary payer for all services, with the exception of those covered and payable by workers' compensation. In 1980, the Congress enacted the first of a series of provisions that made Medicare the secondary payer to certain additional primary plans. These provisions are known as the Medicare

Secondary Payer (MSP) provisions and are found in section 1862(b) of the Social Security Act (the Act).

When specific conditions are met, these provisions in part prohibit Medicare from making payment if payment has been made or can reasonably be expected to be made by a workers' compensation law or plan, automobile and liability insurance (including self-insurance), or no-fault insurance. If payment has not been made or cannot reasonably be expected to be made promptly, Medicare is permitted to make conditional payments (that is, Medicare pays for medical claims with the expectation that it will be repaid if the beneficiary obtains a "settlement"). This is because, if Medicare makes conditional payments, the MSP statute imposes an obligation on the Secretary to recover those conditional payments, once it is established that another individual or entity is responsible for primary payment.

Primary payment responsibility on the part of workers' compensation, liability insurance (including self-insurance), and no-fault insurance is generally demonstrated by settlements, judgments, awards, or other payments. When a "settlement" occurs, the "settlement" is subject to the MSP statute because a "payment has been made" with respect to medical care related to that "settlement." By law, Medicare is subrogated to any right of an individual or any other entity to payment for items or services under a primary plan, to the extent of Medicare's payments for such medical items and services. Moreover, section 1862(b)(2)(B)(iii) of the Act provides a direct right of action to recover Medicare's conditional payments. This direct right of action, which is separate and independent from Medicare's statutory subrogation rights, may be brought to recover conditional payments against any or all entities that are or were responsible for making payment for the items and services under a primary plan. The government may also

recover under the direct right of action from any entity that has received payment from a primary plan or the proceeds of a primary plan's payment to any entity.

Under its rights of subrogation and direct right of action, Medicare recovers for conditional payments related to the "settlement," regardless of when the items and services are provided. Further, Medicare is prohibited from making payment when payment has been made (that is, if the beneficiary obtains a "settlement"). Medicare remains the secondary payer until the "settlement" proceeds are appropriately exhausted. It is important to note that the designation future medical care ("future medicals") is a term specifically used to reference medical items and services provided after the date of "settlement."

II. Provisions of the Advanced Notice of Proposed Rulemaking

The primary purpose of this ANPRM is to respond to affected parties' requests for guidance on "future medicals" MSP obligations, specifically, how individuals/beneficiaries can satisfy those obligations effectively and efficiently. Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), established mandatory MSP reporting obligations. Liability insurance (including self-insurance), no-fault insurance, and workers' compensation laws or plans are required to submit information, as specified by the Secretary, to Medicare related to claims resolved through "settlements," regardless of whether or not there is a determination or admission of liability (see 42 U.S.C. 1395y(b)(8)). While the topic of this ANPRM does not relate to the section 111 of the MMSEA reporting obligations directly, Medicare's ongoing section 111 of the MMSEA implementation efforts, as well as industry efforts to ensure compliance with section 111 of the MMSEA, have sensitized affected parties to other MSP obligations, specifically reimbursement obligations that have been long ignored or

overlooked. As a result, affected parties are requesting clarity regarding "future medicals" MSP obligations and how to resolve them.

Currently, individuals involved in certain workers' compensation situations are able to use Medicare's formal, yet voluntary, Medicare Set-Aside Arrangement (MSA) review process in order to determine if a proposed set-aside amount is sufficient to meet their MSP obligations related to "future medicals." To date, Medicare has not established a similar process for individuals/beneficiaries to use to meet their MSP obligations with respect to "future medicals" in liability insurance (including self-insurance) situations. We are soliciting comment on whether and how Medicare should implement such a similar process in liability insurance situations, as well as comment on the proposed definitions and additional options outlined later in this section. We are further soliciting suggestions on options we have not included later in this section. We are most interested in the feasibility and usability of the outlined options and whether implementation of these options would provide affected parties with sufficient guidance. We want to ensure that the process related to "future medicals" is understandable, efficient, and reflects industry practice, while protecting beneficiaries and the Medicare Trust Funds.

A. CMS Proposed General Rule

If an individual or Medicare beneficiary obtains a "settlement" and has received, reasonably anticipates receiving, or should have reasonably anticipated receiving Medicare covered and otherwise reimbursable items and services after the date of "settlement," he or she is required to satisfy Medicare's interest with respect to "future medicals" related to his or her "settlement" using any one of the following options outlined later in this ANPRM.

B. Proposed Definitions

Several proposed definitions have been developed for use in conjunction with the options Medicare is considering. All definitions have been considered and/or developed for the purposes of this document. We request comment on the definitions of "chronic illness/condition," "physical trauma," and "major trauma," specifically, whether they are accurate and usable in terms of the presumption that future medical care will be required.

We also solicit specific comment on the utility of the definition of "major trauma." The Injury Severity Score (ISS) is one of several methods used to measure the severity of injuries when individuals have sustained more than one traumatic injury. It is generally used in predictive modeling and risk assessments to predict and evaluate emergent care required by an injured individual. We are interested in whether this type of approach is useful in guiding a determination as to whether future medical care will be required and if other approaches are available.

- **Chronic Illness/Condition:** means that the illness/condition persists over a long period of time. The term is generally applied when the course of a disease or condition lasts for more than 3 months. If the individual/beneficiary alleges an injury that is a chronic illness/condition, it is presumed that future medical care will be required. Examples of chronic diseases include, but are not limited to: chronic airflow limitation, including asthma and chronic bronchitis; cancer, diabetes; quadriplegia; and nephrogenic systemic fibrosis.

- **Date of Care Completion:** means the date the individual/beneficiary completed treatment related to his or her "settlement." The individual/beneficiary's treating physician must be able to attest that the individual/beneficiary has completed treatment and that no further medical care related to the "settlement" will be required.

- Future Medical Care ("future medicals"): means Medicare covered and otherwise reimbursable items and services that the individual/beneficiary received after the Date of "Settlement." This definition specifically applies to items and services related to the individual/beneficiary's settlement, judgment, award, or other payment.

- Physical Trauma: refers to an injury (as a wound) to living tissue caused by an extrinsic agent. This also includes blunt trauma, which refers to injury caused by a blunt object or collision with a blunt surface (as in a vehicle accident or fall from a building)

- Major Trauma: major trauma means serious injury to two or more Injury Severity Score (ISS) body regions or an ISS greater than 15. The ISS body regions include the following:

- Head or neck.
- Face.
- Chest.
- Abdomen.
- Extremities.
- External.

C. Proposed Options

Medicare is considering the options listed in this section of the document for developing efficient and effective means for addressing "future medicals." Options 1 through 4 would be available to Medicare beneficiaries as well as to individuals who are not yet beneficiaries.

Options 5 through 7 would be available to beneficiaries only. We request comment on the feasibility and usability of all of the options. We also request proposals for additional options for consideration.

Option 1. The individual/beneficiary pays for all related future medical care until his/her settlement is exhausted and documents it accordingly.

The beneficiary may choose to govern his/her use of his/her settlement proceeds himself/herself. Under this option, he/she would be required to pay for all related care out of his/her settlement proceeds, until those proceeds are appropriately exhausted. As a routine matter, Medicare would not review documentation in conjunction with this option, but may occasionally request documentation from beneficiaries selected at random as part of Medicare's program integrity efforts.

Option 2. Medicare would not pursue "future medicals" if the individual/beneficiary's case fits all of the conditions under either of the following headings:

a. The amount of liability insurance (including self-insurance) "settlement" is a defined amount or less and the following criteria are met:

- The accident, incident, illness, or injury occurred one year or more before the date of "settlement;"

- The underlying claim did not involve a chronic illness/condition or major trauma;
- The beneficiary does not receive additional "settlements;" and
- There is no corresponding workers' compensation or no-fault insurance claim.

b. The amount of liability insurance (including self-insurance) "settlement" is a defined amount or less and all of the following criteria are met:

- The individual is not a beneficiary as of the date of "settlement;"
- The individual does not expect to become a beneficiary within 30 months of the date of "settlement;"

- The underlying claim did not involve a chronic illness/condition or major trauma;

- The beneficiary does not receive additional "settlements;" and
- There is no corresponding workers' compensation or no-fault insurance claim.

We request comment on the appropriate defined amounts to use in Options 2a and 2b, as well as comment on the efficacy of this approach.

Option 3. The individual/beneficiary acquires/provides an attestation regarding the Date of Care Completion from his/her treating physician.

a. Before Settlement--When the individual/beneficiary obtains a physician attestation regarding the Date of Care Completion from his or her treating physician, and the Date of Care Completion is before the "settlement," Medicare's recovery claim would be limited to conditional payments it made for Medicare covered and otherwise reimbursable items and services provided from the Date of Incident through and including the Date of Care Completion. As a result, Medicare's interest with respect to "future medicals" would be satisfied. The physician must attest to the Date of Care Completion and attest that the individual/beneficiary would not require additional care related to his/her "settlement."

b. After Settlement--When the individual/beneficiary obtains a physician attestation from his or her treating physician after settlement regarding the Date of Care Completion, Medicare would pursue recovery for related conditional payments it made from the date of incident through and including the date of "settlement." Further, Medicare's interest with respect to future medical care would be limited to Medicare covered and otherwise reimbursable items and/or services provided from the date of "settlement" through and including the Date of Care Completion. The physician must attest to the Date of Care Completion and attest that the individual/beneficiary would not require additional care related to his/her "settlement." We request comment on the efficacy and feasibility of this option.

Option 4. The Individual/Beneficiary Submits Proposed Medicare Set-Aside Arrangement (MSA) Amounts for CMS' Review and Obtains Approval.

Currently, we have a formal process to review proposed MSA amounts in certain workers' compensation situations. Recently we have received a high volume of requests for official review of proposed liability insurance (including self-insurance) MSA amounts. This has prompted us to consider whether we should implement a formal review process for proposed liability insurance (including self-insurance) MSA amounts. For more information related to workers' compensation MSA process, please visit

[http://www.cms.hhs.gov/Medicare/Coordination-of-](http://www.cms.hhs.gov/Medicare/Coordination-of-Benefits/WorkersCompAgencyServices/wcsetaside.html)

[Benefits/WorkersCompAgencyServices/wcsetaside.html](http://www.cms.hhs.gov/Medicare/Coordination-of-Benefits/WorkersCompAgencyServices/wcsetaside.html). We specifically solicit comment on how a liability MSA amount review process could be structured, including whether it should be the same as or similar to the process used in the workers' compensation arena, whether review thresholds should be imposed, etc.

Option 5. The beneficiary participates in one of Medicare's recovery options.

Recently, we implemented three options with respect to resolving Medicare's recovery claim in more streamlined and efficient manners. Before we issue a demand letter, the beneficiary or his/her representative may participate in one of three recovery options, which allows the beneficiary to obtain Medicare's final conditional payment amount before settlement. The three recovery options are as follows:

- \$300 Threshold-- If a beneficiary alleges a physical trauma-based injury, obtains a liability insurance (including self-insurance) "settlement" of \$300 or less, and does not receive or expect to receive additional "settlements" related to the incident, Medicare will not pursue recovery against that particular "settlement."

- Fixed Payment Option-- When a beneficiary alleges a physical trauma-based injury, obtains a liability insurance (including self-insurance) "settlement" of \$5,000 or less, and does not receive or expect to receive additional "settlements" related to the incident, the beneficiary may elect to resolve Medicare's recovery claim by paying 25 percent of the gross "settlement" amount.

- Self-Calculated Conditional Payment Option--When a beneficiary alleges a physical trauma-based injury that occurred at least 6 months prior to electing the option, anticipates obtaining a liability insurance (including self-insurance) "settlement" of \$25,000 or less, demonstrates that care has been completed, and has not received nor expects to receive additional "settlements" related to the incident, the beneficiary may self-calculate Medicare's recovery claim. Medicare would review the beneficiary's self-calculated amount and provide confirmation of Medicare's final conditional payment amount.

Each of the options is employed in such a way that Medicare's interest with respect to future medicals is, in effect, satisfied for the specified "settlement." Therefore, when a beneficiary participates in any one of these recovery options, the beneficiary has also met his/her obligation with respect to future medicals. We solicit comment on proposed expansions of these options and the justification for that proposed expansion, as well as any suggestions about how to improve the three options we recently implemented.

Option 6. The Beneficiary Makes an Upfront Payment.

We are currently considering two variations of an "upfront payment option."

- a. If Ongoing Responsibility For Medicals was imposed, demonstrated or accepted and medicals are calculated through the life of the beneficiary or the life of the injury.

If ongoing responsibility for medicals was imposed, demonstrated or accepted from the date of "settlement" through the life of the beneficiary or life of the injury, we may review and approve a proposed amount to be paid as an upfront lump sum payment for the full amount of the calculated cost for all related future medical care. This option would generally apply in workers' compensation, no-fault insurance situations or when life-time medicals are imposed by law. In effect, this option may be used in place of administering a MSA if we have reviewed and approved a proposed MSA amount. We solicit comment on how to develop this process, the efficacy of it, and whether it would be utilized.

b. If Ongoing Responsibility for Medicals was Not Imposed, Demonstrated or Accepted.

If a beneficiary obtains a "settlement," our general rule stated previously applies to the "settlement," and ongoing responsibility for medicals has not been imposed on, demonstrated by or accepted by the defendant, the beneficiary may elect to make an upfront payment to Medicare in the amount of a specified percentage of "beneficiary proceeds." This option would most often apply in liability insurance (including self-insurance situations, primarily due to policy caps. For the purposes of this option, the term "beneficiary proceeds" would be calculated by subtracting from the total "settlement" amount attorney fees and procurement costs borne by the beneficiary, Medicare's demand amount (for conditional payments made by Medicare), and certain additional medical expenses the beneficiary paid out of pocket. Such additional medical expenses are specifically limited to items and services listed in 26 U.S.C. 213 (d)(1)(A) through (C) and 26 U.S.C. 213 (d)(2). The calculation of beneficiary proceeds does not include medical expenses paid by, or that are the responsibility of, a source other than the beneficiary. We specifically solicit comment on how to develop this process, its efficacy, and whether it would be utilized.

We further request comment on the calculation of beneficiary proceeds, the appropriate percentage(s) to be used, and how the percentage(s) is/are justified.

Option 7. The Beneficiary Obtains a Compromise or Waiver of Recovery.

If the beneficiary obtains either a compromise or a waiver of recovery, Medicare would have the discretion to not pursue future medicals related to the specific "settlement" where the compromise or waiver of recovery was granted. If the beneficiary obtains additional "settlements," Medicare would review the conditional payments it made and adjust its claim for past and future medicals accordingly. We specifically solicit comment on whether this approach is practical and usable, as it relates to "future medicals."

Again, we also solicit comment on additional options we may consider in order to provide workable solutions for beneficiaries with respect to resolving "future medicals" obligations.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

CMS-6047-ANPRM

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and
Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: April 24, 2012

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: May 8, 2012

Kathleen Sebelius,

Secretary.

Department of Health and Human Services

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CMS-6047-ANPRM

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